



UNITED STATES PATENT AND TRADEMARK OFFICE

A

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,586	09/26/2003	John D. Puskas	16294-0137 (52433-292707)	8660
23370	7590	03/21/2005	EXAMINER	
JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET ATLANTA, GA 30309			MULLEN, KRISTEN DROESCH	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 03/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/672,586

Applicant(s)

PUSKAS, JOHN D.

Examiner

Kristen Mullen

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/22/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 31-60, 75-102 and 131-185 is/are pending in the application.
- 4a) Of the above claim(s) 1-15, 75-102, 145, 146 and 151-154 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 131-144 and 155-184 is/are allowed.
- 6) ☒ Claim(s) 31-59, 147-150 and 185 is/are rejected.
- 7) ☒ Claim(s) 45 and 60 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 31-32, 34, 44, 46, 47, 49, 59, 147, 149 and 185 are rejected under 35

U.S.C. 102(b) as being anticipated by Adams (5,792,187).

With respect to claims 31 and 185, Adams shows a method for stimulating a vagus nerve of a patient, comprising the steps of inserting an electrode (36, 38) into the jugular vein of said patient, and actuating said electrode to create an electrical field effective to stimulate said vagus nerve (Col. 4, line 62-Col. 5, line 5)..

Regarding claim 32, and 147, Adams shows the step of inserting an electrode into the jugular vein of said patient comprises the step of inserting a first electrode (36) into the jugular vein of said patient; wherein said method comprises the further step of inserting a second electrode (38) into the jugular vein of said patient in spaced apart relation to said first electrode; and wherein said step of actuating said electrode to create an electrical field comprises the step of actuating at least one of said first and second electrodes to create an electrical field (Col. 4, line 62-Col. 5, line 5).

With respect to claims 34, and 49 Adams further shows the step of actuating at least one of said electrodes to create an electrical field comprises the step of actuating both of said first and second electrodes to create an electrical field.

Art Unit: 3762

Regarding claims 44 and 59, Adams further shows the said vagus nerve is stimulated during an electrophysiological procedure (defibrillation).

With respect to claims 46 and 185, Adams shows a method for stimulating a vagus nerve of a patient, comprising the steps of positioning an electrode (66, 68) on the neck of said patient; and actuating said electrode to create an electrical field effective to stimulate said vagus nerve (Col. 5, lines 36-39, lines 51-57).

Regarding claim 47 and 149, Adams shows the step of positioning an electrode on the neck of said patient comprises the step of positioning a first electrode (66) on the neck of said patient; wherein said method comprises the further step of positioning a second electrode (68) on the neck of said patient in spaced apart relation to said first electrode; and wherein said step of actuating said electrode to create an electrical field comprises the step of actuating at least one of said first and second electrodes to create an electrical field (Col. 5, lines 36-39, lines 51-57).

The introductory statement of intended use has been carefully considered but is not considered to impart any further method step limitations over the prior art.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 33, 35-43, 48, and 50-58, 148, and 150 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams (5,792,187).

With respect to claim 33, and 148 Adams discloses the claimed invention except for the step of inserting a second electrode into the jugular vein of the patient approximately one centimeter from said first electrode. It would have been an obvious design choice to one with ordinary skill in the art at the time of the invention to insert a second electrode into the jugular vein of the patient approximately one centimeter from said first electrode, since applicant has not disclosed that this particular placement provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any placement such as the placement taught by Adams for stimulating the left and right vagus nerves.

Regarding claims 35 and 50, Adams discloses the claimed invention except for the step of actuating one or both of said electrodes in one of a unipolar or a bipolar mode. It would have been an obvious design choice to one with ordinary skill in the art at the time of the invention to actuate one or both of said electrodes in one of a unipolar or a bipolar mode, since applicant has not disclosed that this unipolar or bipolar mode provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any stimulation mode such as the stimulation mode taught by Adams to stimulate the left and right vagus nerves.

With respect to claims 36-37, and 51-52 Adams discloses the claimed invention except for the vagus nerve being stimulated for a period of between about five and about ninety seconds and a period of between about five and about fifteen seconds. It would have been an obvious design choice to one with ordinary skill in the art at the time of the invention to stimulate the vagus nerve for a period of between about five and about ninety seconds and a period of between about five and about fifteen seconds, since applicant has not disclosed that this particular length of time provides any criticality and /or unexpected results and it appears that the invention would

Art Unit: 3762

perform equally well with any stimulation length such as the stimulation length taught by Adams to stimulate the left and right vagus nerves.

With respect to claims 38-40 and 53-55, Adams discloses the claimed invention except for using an electrical impulse having a frequency of between one and five hundred Hertz, between about twenty Hertz and about eighty Hertz, and about forty Hertz. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the electrical impulse frequency as taught by Adams with an electrical impulse frequency of between one and five hundred Hertz, between about twenty Hertz and about eighty Hertz, and about forty Hertz, since applicant has not disclosed that this particular voltage range provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any electrical impulse frequency such as the electrical impulse frequency taught by Adams for stimulating the vagus nerve.

Regarding claims 41 and 56, Adams discloses the claimed invention except for using an electrical impulse having a duration of 0.4 msec. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the electrical impulse duration as taught by Adams with an electrical impulse voltage duration of 0.4 msec, since applicant has not disclosed that this particular duration of electrical impulse provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any electrical impulse duration such as the electrical impulse duration taught by Adams for stimulating the vagus nerve.

With respect to claims 42-43, and 57-58, Adams discloses the claimed invention except for using an electrical impulse having an amplitude from about one to forty volts and two to six

Art Unit: 3762

volts. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the electrical impulse voltage amplitude as taught by Adams. with an electrical impulse voltage amplitude from about one to forty volts and two to six volts, since applicant has not disclosed that this particular voltage range provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any electrical impulse voltage amplitude such as the electrical impulse voltage amplitude taught by Adams for stimulating the vagus nerve.

With respect to claim 47, and 150 Adams discloses the claimed invention except for the step of positioning a second electrode on the neck of the patient approximately one centimeter from said first electrode. It would have been an obvious design choice to one with ordinary skill in the art at the time of the invention to position a second electrode on the neck of the patient approximately one centimeter from said first electrode, since applicant has not disclosed that this particular placement provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any placement such as the placement taught by Adams for stimulating the left and right vagus nerves.

Response to Arguments

5. Applicant's arguments filed 12/22/04 have been fully considered but they are not persuasive. The amendments made to claims 31 and 46 have added statements of intended use. A positive step recitation that would distinguish the claimed subject matter over the prior art has not been added. For these reasons, applicant's arguments are not persuasive. Adams method could be used during a beating heart surgery. As is well known in the art, during the device implantation procedure, the doctor is going to test the device to make sure it works properly

Art Unit: 3762

before closing the incisions (e.g. fibrillation induction). Given the attendant risks of the use of a heart lung machine, the implantation of a defibrillator with vagal stimulator does not require its use, therefore during the surgery the heart would be beating.

Allowable Subject Matter

6. Claims 131-144 and 155-184 are allowed.
7. Claims 45 and 60 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen (formerly Droesch) whose telephone number is 703-605-1185. The examiner can normally be reached on 10:30 am-6:30 pm.

Art Unit: 3762

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


kdm



ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700